

REMARKS

Claim Amendments

Support for all claim amendments is found in the original specification as filed, and there is no new matter presented in any of the claim amendments.

Claims 69-75, 77-90, and 93-119 are currently pending in the application. In the present Supplemental Amendment, claims 69, 71, 72, 74, 77, 81-86, 100, 101, and 117 are amended, and claims 76, 91, 92, and 120-135 are canceled. Claims 1-68 were previously canceled. Claims 104, 105, and 107-116 were previously withdrawn and are now re-entered for consideration.

Claims 120-135 were subject to a restriction requirement and were previously withdrawn from consideration as directed to a non-elected invention. In the present Supplemental Amendment, claims 120-135 are canceled. Applicant reserves the right to pursue the subject matter of these claims and all other cancelled claims in continuing applications.

Claims 104-116 were subject to an election of species requirement, and claim 106 was elected for examination. Claims 104, 105, and 107-116 were withdrawn from consideration as directed to non-elected species. Since the Examiner has indicated that a generic claim is allowable, species claims 104, 105, and 107-116 are now reintroduced for consideration in the present Supplemental Amendment.

Claim 69

For the Examiner's convenience, a clean version of amended claim 69 is reproduced below.

69. (Currently Amended) A high-throughput system for rapidly determining the proliferative status of primitive hematopoietic cells by luminescence output comprising:

- a. a target cell population of mononuclear cells comprising primitive hematopoietic cells;
- b. a medium comprising serum and methyl cellulose;
- c. a proliferation agent specific for a single subpopulation of primitive hematopoietic cells, the proliferation agent comprising one or more growth factors, one or more cytokines, or combinations thereof;
- d. a reagent capable of reacting with ATP and generating luminescence in the presence of ATP; and
- e. a plate;

wherein the target cell population, the medium, the proliferation agent, and the reagent capable of reacting with ATP are combined in an order to determine the proliferative status of the subpopulation of primitive hematopoietic cells by detecting the level of luminescence generated from the reagent that reacted with the ATP, and

wherein the level of luminescence detected indicates the amount of ATP in the subpopulation of primitive hematopoietic cells, and the amount of ATP in the subpopulation of primitive hematopoietic cells indicates the proliferative status of the subpopulation of primitive hematopoietic cells.

Claim 69 has been amended to specifically recite that the claimed system is a “high-throughput system for rapidly determining the proliferative status of primitive hematopoietic cells.” Support for this amendment is found throughout the specification as filed. Specifically, support can be found at page 18, lines 1-3, and at page 22, in the section entitled “High-throughput assay methods for determining the proliferative status of a target cell population.”

Also in claim 69, the terms “serum mix” and “methyl cellulose mix” have been deleted, and the terms serum and methyl cellulose are now used, clarifying the meaning of the claim.

Claim 69 has been amended to clarify the term “proliferation agent” as “comprising one or more growth factors, one or more cytokines, or combinations thereof.” Support for contacting the primitive hematopoietic cell population with one or more growth factors, one or more cytokines, or combinations thereof is found throughout the application as originally filed, and specifically at page 15, lines 2-17; page 18, lines 11-22; page 23, line 19 - page 24, line 4, for example. Numerous specific examples of the use of one or more growth factors and/or cytokines are provided at page 29, line 6 - page 30, line 24; Example 3, page 51; and Table 3, page 52.

Support for use of the term “proliferation agent” appears throughout the application and specifically on page 15, lines 2-17 of the application as filed. Additional examples of support from the specification as filed are specifically recited in the Amendment and Response dated 10 September 2007.

Claim 69 has been amended to recite a “reagent capable of reacting with ATP and generating luminescence in the presence of ATP.” Claim 69 has also been amended to recite “the reagent that reacted with the ATP” to clarify that the reagent reacts with ATP in order produce luminescence. Support for these amendments is found throughout the specification and specifically in Example 2, page 49, line 4 - page 51, line 21. This example explains how ATP is released from the cells in order to react with the reagents used to quantify the levels of ATP in the cells.

Finally, Claim 69 has been amended to clarify the correlation between the level of ATP detected and the proliferative status of the cells. Support for this amendment is found, for example, at page 7, lines 19-29; page 18, lines 1-10; page 31, lines 9-14; page 32, lines 17-24; Example 2 at page 49, line 4 - page 51, line 21; and Example 4 at page 53 line 1 - page 54, line 15.

Claim 71

Claim 71 has been amended provide proper antecedent basis in view of the amendments to claim 69. The term “hematotoxicity” has also been deleted from claim 71 because the Examiner has issued a restriction requirement requiring the Applicant to elect either (a) “determining the proliferative status” or (b) “determining the hematotoxicity” of the subpopulation of primitive hematopoietic cells.

Claim 72

Claim 72 has been amended to add the term “further comprises” in view of the amendments to claim 69.

Claim 74

Claim 74 has been amended to provide proper antecedent basis in view of the amendments to claim 69.

Claim 76

Claim 76 has been canceled.

Claim 77

Claim 77 has been amended to depend from claim 69 rather than from claim 76 in view of the cancellation of claim 76. Claim 77 has been amended to provide proper antecedent basis for the “reagent capable of reacting with ATP and generating luminescence in the presence of ATP” in view of the amendments to claim 69. Finally the phrase “wherein the level of luminescence correlates to the amount of ATP in the target cell population, and the amount of ATP correlates to the proliferative status of the target cell population” has been deleted from claim 77 in order to avoid redundancy, as this phrase has been incorporated into claim 69.

Claims 81-86

Claims 81-86 have been amended to add the term “further comprises” in view of the amendments to claim 69.

Claims 91 and 92

Claims 91 and 92 have been canceled due to redundancy.

Claims 100 and 101

Claims 100 and 101 have been amended to provide proper antecedent basis for the “single subpopulation of primitive hematopoietic cells” in view of the amendments to claim 69.

Claims 104, 105, and 107-116

Claims 104-116 were subject to an election of species requirement, and claim 106 was initially elected for examination. Claims 104, 105, and 107-116 were withdrawn from consideration as directed to non-elected species. Since the Examiner has indicated that a generic claim is allowable, species claims 104, 105, and 107-116 are now reintroduced for consideration in the present application.

Claim 117

Claim 117 has been amended to depend from claim 77 rather than from claim 76 in view of the cancellation of claim 76.

Each of the claim amendments is fully supported by the application as filed, and no new matter has been introduced through the claim amendments.

Claim Rejections from the Office Action dated 9 April 2007

Each of these rejections was fully addressed in the Applicant's Amendment and Response filed on 10 September 2007. The Applicant, nonetheless, addresses some of these rejections again here, as the current claim amendments have rendered many of these earlier rejections moot.

A. Rejection of claims 69-103, 106, and 117-119 under 35 U.S.C. § 112, second paragraph, as being indefinite

The Examiner rejected claims 69-103, 106, and 117-119 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

1. Rejection of claim 69 under 35 U.S.C. § 112, second paragraph, as being indefinite in reciting "serum mix"

The Examiner objected to the use of the term "serum mix" in claim 69 as being indefinite. Amended claim 69 recites "serum" rather than "serum mix." Therefore, the rejection is moot in view of the amendment to claim 69.

2. Rejection of claim 69 under 35 U.S.C. § 112, second paragraph, as being indefinite in reciting “methyl cellulose mix”

The Examiner objected to the use of the term “methyl cellulose mix” in claim 69 as being indefinite. Amended claim 69 recites “methyl cellulose” rather than “methyl cellulose mix.” Therefore, the rejection is moot in view of the amendment to claim 69.

3. Rejection of claim 69 under 35 U.S.C. § 112, second paragraph, as being indefinite in reciting “a mix of growth factors” and “a mix of cytokines”

The Examiner objected to the use of the terms “a mix of growth factors” and “a mix of cytokines” in claim 69 as being indefinite. These terms have been deleted from claim 69. Amended claim 69 recites a “proliferation agent comprising one or more growth factors, one or more cytokines, or combinations thereof.” This amendment to claim 69 renders this rejection moot. Support for this amendment is discussed above.

4. Rejection of claim 74 under 35 U.S.C. § 112, second paragraph, as being indefinite in reciting “IMDM”

The Examiner had rejected claim 74 as being indefinite in reciting “IMDM” because IMDM is an acronym. In the Amendment and Response dated 10 September 2007, claim 74 was amended to define the acronym IMDM as “Iscove’s modified Dulbecco’s medium.” Support for this amendment is discussed in the Amendment and Response dated 10 September 2007. In view of the earlier amendment to claim 74, this rejection is moot.

5. Rejection of claim 77 under 35 U.S.C. § 112, second paragraph

The Examiner rejected claim 77 as being confusing in relation to the claims from which it depends. This rejection was related to the Examiner's rejection of claim 69 as being indefinite for the use of the terms "serum mix" and "methyl cellulose mix." As discussed above, claim 69 no longer recites these terms. Amended claim 69 recites "serum" and "methyl cellulose," rendering this rejection moot.

The remaining rejections in the Office Action mailed 9 April 2007 were the following art-based rejections.

- B. Rejection of claims 69-73 under 35 U.S.C. § 103(a) as being unpatentable over Bell et al., U.S. Patent Application Publication No. US 2002/0120098 A1, in view of Crouch et al., *Journal of Immunological Methods*, 160: 81-88 (1993).
- C. Rejection of claims 74-102, 106, and 117-119 under 35 U.S.C. § 103(a) as being unpatentable over Bell et al., in view of Crouch et al., and further in view of Tang et al., U.S. Patent No. 6,824,973.

These art-based rejections from the Office Action dated 9 April 2007 are not addressed here because they have been fully addressed in the personal interview with the Examiner on 21 August 2007 and in the Amendment and Response dated 10 September 2007.

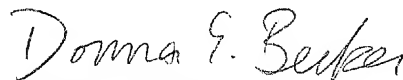
Conclusion

Any amendments made during the prosecution of this application are intended to expedite prosecution of the application and are not to be interpreted as acknowledgement of the validity of any rejection raised earlier in prosecution, nor as acknowledgement that any citation made against the application is material to the patentability of the application prior to amendment.

No additional fees are believed necessitated by the filing of this Supplemental Amendment. Should any such additional fees be required, the Director is hereby authorized to deduct them from Deposit Account No. 18-2000, of which the undersigned is an authorized signatory.

Should the Examiner believe that there are any outstanding matters capable of resolution by a telephone interview, the Examiner is encouraged to telephone the undersigned attorney of record. Finally, the Applicant and the Applicant's Attorney thank the Examiner for the Examiner's time and consideration.

Respectfully submitted,



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